

Application No.: 10/052,077  
Reply to Office Action mailed February 9, 2005

### **REMARKS/ARGUMENTS**

The office action of February 9, 2005 has been carefully reviewed and these remarks are responsive thereto. Reconsideration and allowance of the instant application are respectfully requested.

Claims 1-12 and 14-33 are pending. The Office Action objected to the specification for failing to provide proper antecedent basis for claimed subject matter. The Office Action also objected to the drawings. Claims 1-12 and 14-33 were rejected under 35 U.S.C. § 103(a) as being unpatentable in light of U.S. Patent No. 4,604,089 to Santangelo *et al.* ("Santangelo") in view of U.S. Patent No. 4,447,224 to DeCant, Jr. *et al.* ("DeCant").

In response, Applicants provide the following remarks and respectfully traverse all objections and rejections.

#### **Objections to the Specification**

The specification was objected to as failing to provide proper antecedent basis for the claimed subject matter, specifically the terms "a flow limiter" and "passive flow rate control elements."

In a prior response mailed November 16, 2004, the phrase "flow limiter" of claim 15 was replaced with the phrase "flow restrictor." Therefore, the Applicants have been unable to find the term "flow limiter" in the pending claims. Accordingly, Applicants believe that the term "flow limiter" cannot support an objection under either 37 CFR 1.75(d)(1) or MPEP § 608.01(o).

The term "passive flow rate control elements" is found in the claims. However, in the prior response mailed November 16, 2004 the Applicants amended paragraph 5 to provide what the Applicants believe is explicit antecedent basis for the term "passive flow rate control elements."

Accordingly, Applicants believe the requirements of 37 CFR 1.75(d)(1) and MPEP § 608.01(o) have been met for the above terms and withdrawal of the objection is respectfully requested.

#### **Informality in the Specification**

The Examiner indicated that he believed that the Applicants were invoking 35 U.S.C. § 112, ¶ 6 in claims 19 and 26, for example. The Office Action objected to the specification for

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failing to explicitly state what structure and materials performed the means and requested that the specification be amended to more explicitly state what structure performed the recited functions.

The Applicants have reviewed the cited sections in the CFR and the MPEP and respectfully assert that the specification, for example paragraphs 21-22 and FIG 4, make it clear to one of skill in the art what the "means" refers to and therefore the specification and drawings meet the requirements of 37 CFR 1.75(d)(1), MPEP § 608.01(o) and MPEP § 2181. Indeed, the MPEP explains that:

However, 35 U.S.C. § 112, sixth paragraph does not impose any requirements in addition to those imposed by 35 U.S.C. § 112, first paragraph.

MPEP § 2181 (II) (May 2004 Revision). Therefore, the Office Action's request for additional comments does not appear to be a requirement under the current version of the MPEP. Accordingly, withdrawal of this objection is respectfully requested.

#### **Objection to the Drawings**

The drawings were objected to as failing to comply with 37 CFR 1.84(p)(5), apparently because they do not include reference characters that are referred to as a first and second "passive flow rate control elements." The Applicants respectfully submit that this objection is not supported by 37 CFR 1.84(p)(5). The Applicants understand that the drawings must show every limitation recited in the claims and that any numerical reference in the drawing must be referred to in the specification. However, Applicants are not aware of any requirement to include numerical references in the drawings that precisely match terms recited in the claims.

Applicants previously amended paragraph 5 to provide antecedent basis for the term "passive flow rate control elements" in the prior Response mailed November 16, 2004. Thus, element 102 of FIG. 1 is an example of a passive flow rate control element. Accordingly, Applicants believe that the drawings show all the limitations recited in the claims and that every numerical reference referred to in the drawings has been discussed in the specification.

As all the requirements of 37 CFR 1.84 in general, and 37 CFR 1.84(p)(5) specifically, are believed to be satisfied with the current drawings and specification, withdrawal of this objection is respectfully requested.

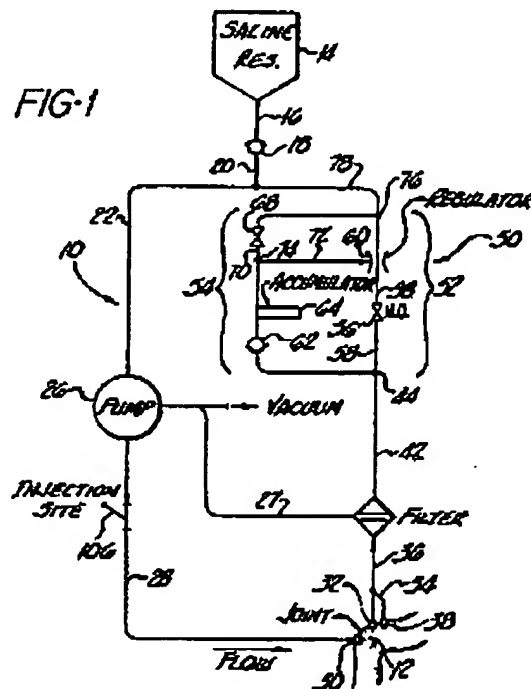
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### Rejection under 35 U.S.C. § 103(a)

Independent claims 1, 6, 11, 14 and 21 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Santangelo in view of DeCant.

As an initial matter, the Applicants respectfully submit that there is no motivation to combine the Santangelo reference with the DeCant reference.

FIG. 1 of Santangelo is provided below.



Santangelo explains that the pressure accumulation branch 54 and the flow restriction branch 52 are used to provide a pressure regulation circuit 50. (Santangelo, C. 4, L. 11-29). The purpose of the pressure regulation circuit 50 is to control the pressure experienced by the joint 12. (Santangelo, C. 4, L. 42-56). However, building up pressure at the site of delivery (e.g. joint 12) as taught by Santangelo would be unsafe to use within a patient, especially in an implantable pump as recited in all the pending claims. Therefore, one would not look to Santangelo for aid in designing a control for an implantable pump. Thus, there would be no motivation to combine Santangelo with DeCant. See MPEP 706.02(j) ("To establish a *prima facie* case of obviousness,

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three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings."'). Accordingly, for at least this reason alone it is respectfully submitted that the combination of Santangelo and DeCant fails to support a *prima facie* case of obviousness.

In addition, the pressure regulation circuit 50 of Santangelo would simply not function with the pump of DeCant. Figure 1 of Santangelo is provided above and as previously explained, regulates pressure rather than flow. Figure 1 of DeCant is provided below:

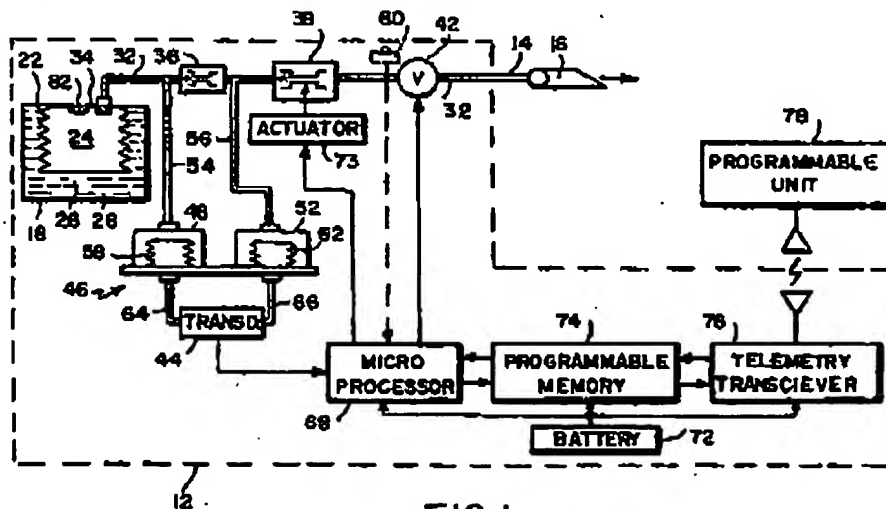


FIG. 1

Even assuming there was some type of motivation to place the pressure regulation circuit 50 of Santangelo between the chamber 24 and the catheter 16, such a device would not function properly. As explained by DeCant, the fluid in chamber 24 is under constant pressure due to a two-phase liquid 28 that vaporizes at physiological temperatures. (DeCant, (C. 5, L. 43-50). Therefore, the pressure regulation circuit 50 of Santangelo, which regulates pressure and is designed to operate with a constant flow pump, would not be able to modify the flow rate in a desired manner. Put another way, the pressure regulator circuit 50 of Santangelo would not modify the pressure of fluid provided by the constant pressure pump of DeCant. Accordingly, a person of skill in the art looking at DeCant and Santangelo would not expect the combination to work when combined. See MPEP 706.02(j) ("To establish a *prima facie* case of obviousness, three basic criteria must be met. ... Second, there must be a reasonable expectation of success.).

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Indeed, Applicants cannot readily envision a manner in which the pressure regulator circuit 50 of Santangelo could be modified to make it work with the constant pressure pump of DeCant. Therefore, for at least this additional reason the combination of Santangelo and DeCant fails to support a *prima facie* case of obviousness for pending claim.

Therefore, it is respectfully submitted that the combination of Santangelo and DeCant fails to support a *prima facie* case of obviousness for the pending independent claims 1, 6, 11, 14 and 21. All remaining pending claims depend from one of these pending claims, thus, for at least the reasons discussed above the dependent claims are also nonobvious in view of the combination of Santangelo and DeCant. Accordingly, withdrawal of this ground of rejection is requested.

### CONCLUSION

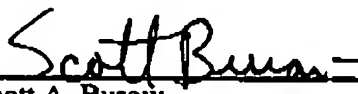
It is believed that all claims are in allowable condition and that no fee is required for this submission. If any fees are required or if an overpayment is made, the Commissioner is authorized to debit or credit our Deposit Account No. 19-0733, accordingly.

All rejections and objections having been addressed, Applicants respectfully submit that the instant application is in condition for allowance, and respectfully solicits prompt notification of the same.

Respectfully submitted,  
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Dated: May 3, 2005

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